



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2023-C-1487]

### Filing of Color Additive Petition from Environmental Defense Fund, et al.; Request To Revoke Color Additive Listing for Use of Titanium Dioxide in Food; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of petition; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the color additive petition for which we published a notice of filing in the *Federal Register* on May 3, 2023. In the notice, FDA requested comments on a filed color additive petition submitted by Environmental Defense Fund, et al., proposing that FDA repeal the color additive regulation providing for the use of titanium dioxide in foods. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the color additive petition for which a notice of filing was published in the *Federal Register* of May 3, 2023 (88 FR 27818). Either electronic or written comments must be submitted by September 1, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 1, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-C-1487 for "Filing of Color Additive Petition From Environmental Defense Fund, et al.; Request To Revoke Color Additive Listing for Use of Titanium Dioxide in Food." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for

those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Paulette M. Gaynor, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1192.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of May 3, 2023 (88 FR 27819), we published a notice of filing of a color additive petition with a 60-day comment period. We explained that, under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we were giving notice that we had filed a color additive petition (CAP 3C0325), submitted by Environmental Defense Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, and Environmental Working Group, c/o Tom Neltner, 1875 Connecticut Ave., NW, Washington, DC 20009. The color additive petition proposes that we repeal the color additive regulation for titanium dioxide in 21 CFR 73.575, which permits the use of titanium dioxide in foods.

We have received requests for a 60-day extension of the comment period for the color additive petition. We have considered these requests and are extending the comment period for the color additive petition until September 1, 2023. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying a response to this petition.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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